

**CARE ONE MIGRAINE RELIEF- acetaminophen, aspirin and caffeine tablet, film coated**  
**American Sales Company**

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**American Sales Company Migraine Relief Drug Facts**

**Active ingredients (in each caplet)**

Acetaminophen 250 mg

Aspirin 250 mg (NSAID\*)

Caffeine 65 mg

\*nonsteroidal anti-inflammatory drug

**Purposes**

Pain reliever

Pain reliever aid

**Use**

- treats migraine

**Warnings**

**Reye's syndrome:** Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

**Allergy alert:** Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

**Allergy alert:** Aspirin may cause a severe allergic reaction which may include:

- hives
- facial swelling
- asthma (wheezing)
- shock

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take

- more than 2 caplets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

### Stomach bleeding warning:

This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

**Caffeine warning:** The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heart beat.

### **Do not use**

- if you have ever had an allergic reaction to acetaminophen, aspirin or any other pain reliever/fever reducer
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

### **Ask a doctor before use if**

- you have never had migraines diagnosed by a health professional
- you have a headache that is different from your usual migraines
- you have the worst headache of your life
- you have fever and stiff neck
- you have headaches beginning after or caused by head injury, exertion, coughing or bending
- you experienced your first headache after the age of 50
- you have daily headaches
- you have a migraine so severe as to require bed rest
- you have liver disease
- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- you have asthma
- you have problems or serious side effects from taking pain relievers or fever reducers
- you have vomiting with your migraine headache

### **Ask a doctor or pharmacist before use if you are**

- taking a prescription drug for:
- diabetes
- gout
- arthritis

- under a doctor's care for any serious condition
- taking any other drug
- taking any other product that contains aspirin, acetaminophen, or any other pain reliever/fever reducer

### **Stop use and ask a doctor if**

- an allergic reaction occurs. Seek medical help right away.
- you experience any of the following signs of stomach bleeding:
- feel faint
- vomit blood
- have bloody or black stools
- have stomach pain that does not get better
- your migraine is not relieved or worsens after first dose
- new or unexpected symptoms occur
- ringing in the ears or loss of hearing occurs

### **If pregnant or breast-feeding,**

ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

### **Keep out of reach of children.**

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms

### **Directions**

- do not use more than directed
- adults: take 2 caplets with a glass of water
- if symptoms persist or worsen, ask your doctor
- do not take more than 2 caplets in 24 hours, unless directed by a doctor
- under 18 years of age: ask a doctor

### **Other information**

- store at 20°-25°C (68°-77°F)
- close cap tightly after use
- read all product information before using. Keep this box for important information.

### **Inactive ingredients**

carnauba wax, crospovidone, FD&C blue #1 aluminum lake, hypromellose, microcrystalline cellulose, povidone, pregelatinized starch, propylene glycol, saccharin sodium, stearic acid, titanium dioxide

### **Questions or comments?**

1-800-719-9260

## Principal Display Panel

Compare to the Active Ingredients in Excedrin® Migraine

MIGRAINE RELIEF

Acetaminophen, Aspirin (NSAID) and Caffeine Tablets, USP

PAIN RELIEVER/PAIN RELIEVER AID

100 COATED CAPLETS\*\*

\*\*Capsule-shaped Tablets



EXP. DATE :

EXP.

CODE AREA

LOT NO.



## Drug Facts

### Active ingredients (in each caplet)

### Purposes

Acetaminophen 250 mg.....	Pain reliever
Aspirin 250 mg (NSAID)*.....	Pain reliever
Caffeine 65 mg.....	Pain reliever aid
*nonsteroidal anti-inflammatory drug	

**Use** ■ treats migraine

### Warnings

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**Allergy alert:** Acetaminophen may cause severe skin reactions. Symptoms may include:

■ skin reddening ■ blisters ■ rash

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**Allergy alert:** Aspirin may cause a severe allergic reaction which may include: ■ hives

■ facial swelling ■ asthma (wheezing) ■ shock

**Liver warning:** This product contains acetaminophen.

Severe liver damage may occur if you take

■ more than 2 caplets in 24 hours, which is the maximum daily amount ■ with other drugs containing acetaminophen ■ 3 or more alcoholic drinks every day while using this product

**Stomach bleeding warning:** This product contains an NSAID, which may cause severe stomach bleeding.

The chance is higher if you ■ are age 60 or older

■ have had stomach ulcers or bleeding problems

■ take a blood thinning (anticoagulant) or steroid drug

■ take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) ■ have 3 or more alcoholic drinks every day while using this product ■ take more or for a longer time than directed

## Drug Facts (continued)

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**Do not use** ■ if you have ever had an allergic reaction to acetaminophen, aspirin or any other pain reliever/fever reducer ■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist

### Ask a doctor before use if

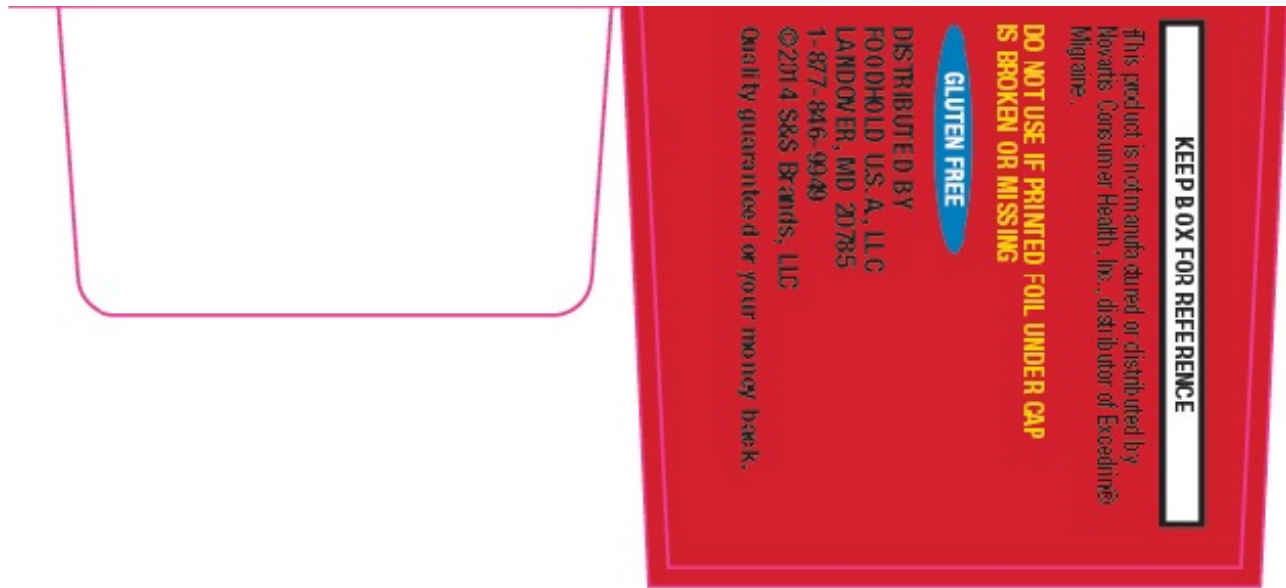
■ you have never had migraines diagnosed by a health professional ■ you have a headache that is different from your usual migraines ■ you have the worst headache of your life ■ you have fever and stiff neck ■ you have headaches beginning after or caused by head injury, exertion, coughing or bending ■ you experienced your first headache after the age of 50 ■ you have daily headaches ■ you have a migraine so severe as to require bed rest ■ you have liver disease ■ stomach bleeding warning applies to you ■ you have a history of stomach problems, such as heartburn ■ you have high blood pressure, heart disease, liver cirrhosis, or kidney disease ■ you are taking a diuretic ■ you have asthma ■ you have problems or serious side effects from taking pain relievers or fever reducers ■ you have vomiting with your migraine headache

### Ask a doctor or pharmacist before use if you are

■ taking a prescription drug for:  
■ diabetes ■ gout ■ arthritis  
■ under a doctor's care for any serious condition  
■ taking any other drug  
■ taking any other product that contains aspirin, acetaminophen, or any other pain reliever/fever reducer

### Stop use and ask a doctor if

■ an allergic reaction occurs. Seek medical help right away.



<b>CARE ONE MIGRAINE RELIEF</b>			
acetaminophen, aspirin, caffeine tablet, film coated			
<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-374
Route of Administration	ORAL	DEA Schedule	
<b>Active Ingredient/Active Moiety</b>			
Ingredient Name		Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)		ACETAMINOPHEN	250 mg
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)		ASPIRIN	250 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)		CAFFEINE	65 mg
<b>Inactive Ingredients</b>			
Ingredient Name			Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)			
CROSPVIDONE (UNII: 68401960MK)			
HYPMELLOSES (UNII: 3NXW29V3WO)			
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)			
POVIDONES (UNII: FZ989GH94E)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
SACCHARIN SODIUM (UNII: SB8ZUX40TY)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
<b>Product Characteristics</b>			
Color	WHITE	Score	no score
Shape	CAPSULE	Size	17mm

<b>Flavor</b>		<b>Imprint Code</b>	L374
<b>Contains</b>			
<b>Packaging</b>			
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>
1	NDC:41520-374-78	1 in 1 CARTON	
1		100 in 1 BOTTLE	
2	NDC:41520-374-62	1 in 1 CARTON	
2		24 in 1 BOTTLE	
<b>Marketing Information</b>			
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA075794	04/13/2004	

**Labeler** - American Sales Company (809183973)